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10/674,205	09/29/2003	Steffen Hansen	6415.200-US	2513

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NOVO NORDISK, INC.
INTELLECTUAL PROPERTY DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER

RAJ, RAJIV J

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/674,205
Filing Date: September 29, 2003
Appellant(s): HANSEN et al.

Marc A. Began Reg. 48,829
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 19 May 2009 appealing from the Office action mailed 22 September 2008.

(1) Real Party in Interest

The real party of interest in this appeal is Novo Nordisk A/S, of Bagsvaerd, Denmark.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

NEW GROUND(S) OF REJECTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 contain a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not seem to delineate a "means for delivering", "first processor means", "first transmission means", "receiving means in the indicating device", "first receiving means", "memory means", "timer means", "second processor means", nor a "indication means". Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function

and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4146029	Ellinwood, Jr.	3-1979
5764159	Neftel	6-1998
6592519 B1	Martinez	7-2003

Applicant's Own Admission (AOA) "Background of the Invention"

(9) Grounds of Rejection

Claim Rejections - 35 USC § 112 (New Grounds)

The following ground(s) of rejection are applicable to the appealed claims:

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 contain a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not seem to delineate a “*mean*” language.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification,

perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (US 4146029) (hereinafter Ellinwood) in view of Neftel (US 5764159) (hereinafter Neftel), in view of Martinez (US 6592519 B1) (hereinafter Martinez) in further view of Applicant's Own Admission (hereinafter AOA).

Claim 1

Ellinwood as shown, discloses the following limitations:

- *a reservoir (111) containing an amount of a liquid drug, (see at least Ellinwood, Jr. Fig.12 Item 254)*
- *means (111, 121) for delivering the drug into a body of a user in accordance with a delivery rate value or profile, (see at least Ellinwood, Fig.21 Item 350-362)*

Ellinwood does not disclose the following limitations, however Neftel, as shown, does:

- *memory means (124) for storing data information, (see at least Neftel Column:8 Lines:5-13 “means for receiving said sequence of control information from said equipment and for storing at least a portion of said sequence of control information in said memorizing means, whereby at least a portion of the control information relating to each of said equipment in association with information identifying said equipment are memorized, said memorized information including at least the information representative of the operating duration of said equipment;”)*
- *timer means (123), (see at least Neftel Column:4 Lines:42-44 “The circuits of the control device 10 also include a clock signal or time base 54 which delivers time pulses on an output 54a that are applied to an input 40a”)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the features of Neftel into Ellinwood. One of ordinary skill in the art would have added these features into Ellinwood, with the motivation of increasing the efficiency of monitoring and administering medication to patients (see at least Neftel Column:1 Lines:22-26).

Ellinwood/Neftel discloses the previous limitations as shown above.

Ellinwood/Neftel does not disclose the following limitation. However Martinez, as shown, discloses:

- *second processor means (122) adapted for calculating a time-dependent estimate for the amount of drug in the reservoir based upon received data*

information and time information from the timer means, and indication means (112) cooperating with the second processor means for indicating a calculated value (see at least Martinez Column:7 Lines:50-67)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the feature of Martinez into Ellinwood/Neftel. One of ordinary skill in the art would have added this feature into Ellinwood/Neftel with the motivation to provide a more effective and accurate system for remotely monitoring and controlling the amount of medication administered to a patient from a particular medical instrument.

Ellinwood/Neftel/Martinez discloses the previous limitations as shown above.

Ellinwood/Neftel/Martinez does not disclose the following limitations. However AOA, as shown, discloses:

- *first processor means (121), and first transmission means (131) cooperating with the first processor means for transmitting data information to receiving means in the indicating device, the indicating device comprising: (AOA [0009] “the drug infusion device to transmit confirmation or these settings and commands back to the programmer. The return communication link also allows the drug infusion unit to transmit status information back to the programmer”)*
- *first receiving means (132) for receiving data information transmitted from the delivery device, (AOA [0008] “The monitor can be operated in response to information received and/or displayed from either the pump or the glucose*

sensor to thereby control pump operation through the use of radio telemetry signals.”)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the features taught by AOA into Ellinwood/Neftel/Martinez. One of ordinary skill in the art would have added these features into Ellinwood/Neftel/Martinez with the motivation to provide a more effective and efficient process for administering and monitoring a patient’s medication (see at least AOA [0002]).

(10) Response to Argument

In the appeal brief filed 19 May 2009, Appellant makes the following arguments:

Argument 1: Applicant asserts that the Examiner cites prior art that is not analogous to Applicant’s invention.

Argument 2: Applicant asserts that the Examiner cites prior art that fails disclose a “*second processor means adapted for calculating a time—dependent estimate for the amount of drug in the reservoir based upon received data . . .*”.

Argument 3: Applicant asserts that the Examiner’s motivation to modify the prior art fails to address certain limitations in claim 1.

Examiner will address Appellant’s arguments in the order listed.

Response to Argument 1: In response to applicant's argument that the cited prior art is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

Response to Argument 2: Applicant argues that the cited prior art fails to disclose a "*second processor means adapted for calculating a time—dependent estimate for the amount of drug in the reservoir based upon received data . . .*". Examiner has fully considered applicant's arguments and respectfully disagrees. Examiner asserts that "calculating estimate amount of drug" is disclosed by the cited prior art which discloses an invention that measures an amount of insulin, which correlates, to the users present correlating condition. (see at least Martinez Column:2 Lines:41-67 Column:3 Lines:1-67) Further, Examiner points out that the administration of insulin is a "*time dependent*" phenomena.

Response to Argument 3: Applicant argues that the Examiner's motivation to modify the prior art fails to address certain limitations in claim 1. Examiner has fully considered applicant's arguments and they are unpersuasive. Examiners reason to modify the prior art are appropriately addressed in the paragraphs

addressing the motivation to combine. Further, these paragraphs, as written, do address all of the limitations.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Notice to Appellant – Reply is Required

This examiner's answer contains a new ground of rejection set forth in sections (6) and **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/R. J. R./

Rajiv J. Raj
Examiner, Art Unit 3686

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Wynn W. Coggins/

Director, Technology Center 3600

Application: 10/674,205

Paper No. 20100609

Art Unit: 3686

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Conferees:

Gerald J. O'Connor /GJOC/
Supervisory Patent Examiner,
Group Art Unit 3686

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